

AMENDED IN SENATE AUGUST 28, 2006

AMENDED IN ASSEMBLY MAY 26, 2006

AMENDED IN ASSEMBLY APRIL 27, 2006

AMENDED IN ASSEMBLY APRIL 6, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2877

Introduced by Assembly Member Frommer

February 24, 2006

An act to amend Section 14982 of, and to repeal Section 14981 of, the Government Code, and to add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 2877, as amended, Frommer. Prescription drugs: importation: procurement.

(1) Existing law authorizes the Department of General Services to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. Existing law requires specified state agencies to participate in the prescription drug bulk purchasing program. Existing law requires the department to submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been, or will be, undertaken pursuant to these provisions.

This bill would, among other things, require the department to develop strategies for the state to achieve savings through greater use of generic drugs and would revise the ~~report~~ *reporting* requirements.

(2) Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California R Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program ~~and. It would also require the department to establish a Web site on or before July 1, 2007~~ 2008, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would, except as specified, require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical *manufacturer* programs, ~~pharmacies that are located in Canada, the United Kingdom, and Ireland and that meet specified requirements,~~ and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would, ~~except under prescribed circumstances~~ require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state ~~and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.~~ *The bill would provide that the implementation of the program shall be contingent upon an appropriation, if the department determines that the requirements of the program cannot*

be implemented without additional funding, in which case the bill would require the department to request an appropriation from the Legislature for that purpose.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Prescription drugs have become essential for ensuring the
- 4 health of millions of Californians.
- 5 (b) The United States is the largest trade market for
- 6 pharmaceuticals in the world, yet American consumers pay the
- 7 highest prices for brand-name pharmaceuticals in the world.
- 8 (c) Increased spending on prescription drugs is a significant
- 9 driver of increases in overall health care costs, with spending
- 10 nationwide on prescription drugs rising over 15 percent each year
- 11 from 2000 to 2002.
- 12 (d) Rising out-of-pocket costs for prescription drugs are
- 13 placing a growing burden on California consumers, as evidenced
- 14 by federal government statistics that show that in 2002 the
- 15 increase in consumers' out-of-pocket costs for prescription drugs
- 16 was greater than the increase in out-of-pocket costs for all other
- 17 health care expenditures.
- 18 (e) The price of brand-name drugs is rising faster than the rate
- 19 of inflation, with a recent study showing that the price of 30
- 20 drugs most frequently used by the elderly rose by over four times
- 21 the rate of inflation in 2003 and that some drugs increased in
- 22 price by 10 times the rate of inflation in that year.
- 23 (f) The rising cost of prescription drugs jeopardizes the health
- 24 of seniors, the disabled, and other consumers who cannot afford
- 25 the medication they need to stay healthy, as shown by a study by
- 26 the RAND Corporation that found that when out-of-pocket
- 27 payments for prescription drugs doubled, patients with diabetes
- 28 and asthma cut back on their use of drugs by over 20 percent and
- 29 subsequently experienced higher rates of emergency room visits
- 30 and hospital stays.
- 31 (g) The rising cost of prescription drugs places a
- 32 disproportionate burden on communities of color, as shown in a

1 report from the Center for Studying Health System Change that
2 found that African-Americans are about 75 percent and Latinos
3 about 50 percent more likely than nonminorities to not have
4 purchased a prescription drug in 2001 because of cost issues.

5 (h) A prescription drug is neither safe nor effective to an
6 individual who cannot afford it.

7 (i) California residents face a growing need for assistance in
8 finding information about sources for prescription drugs at
9 affordable prices.

10 SEC. 2. Section 14981 of the Government Code is repealed.

11 SEC. 3. Section 14982 of the Government Code is amended
12 to read:

13 14982. (a) It is the intent of the Legislature that the
14 Department of General Services, University of California, and
15 the Public Employees' Retirement System regularly meet and
16 share information regarding each agency's procurement of
17 prescription drugs in an effort to identify and implement
18 opportunities for cost savings in connection with this
19 procurement. It is the intent of the Legislature that the University
20 of California and the Public Employees' Retirement System
21 cooperate with the department in order to reduce each agency's
22 costs for prescription drugs.

23 (b) The department shall do all of the following:

24 (1) Share information on a regular basis with the University of
25 California and the Public Employees' Retirement System
26 regarding each agency's procurement of prescription drugs,
27 including, but not limited to, prices paid for the same or similar
28 drugs and information regarding drug effectiveness.

29 (2) Identify opportunities for the department, the University of
30 California, and the Public Employees' Retirement System to
31 consolidate drug procurement or engage in other joint activities
32 that will result in cost savings in the procurement of prescription
33 drugs.

34 (3) Participate in at least one independent association that
35 develops information on the relative effectiveness of prescription
36 drugs.

37 (4) Develop strategies, in consultation with the affected
38 agencies, for the state to achieve savings through greater use of
39 generic drugs.

1 (5) No later than January 1, 2006, and annually thereafter,
2 develop a workplan that includes, but is not limited to, a
3 description of the department's annual activities to reduce the
4 state's costs for prescription drugs and an estimate of cost
5 savings.

6 (6) No later than January 10, 2006, and annually thereafter,
7 report to the Chairperson of the Joint Legislative Budget
8 Committee and the chairs of the fiscal committees of the
9 Legislature and the appropriate policy committees of the
10 Legislature on activities that have been, or will be, undertaken
11 pursuant to this chapter. The report shall include, but not be
12 limited to, all of the following:

13 (A) The number and a description of contracts entered into
14 with manufacturers and suppliers of drugs pursuant to Section
15 14977.1, including any discounts, rebates, or refunds obtained.

16 (B) The number and a description of entities that elect to
17 participate in the coordinated purchasing program pursuant to
18 Section 14977.5.

19 (C) A description of any joint activities of the department, the
20 University of California, and the Public Employees' Retirement
21 System in the last 12 months in connection with procurement of
22 prescription drugs.

23 (D) Other options and strategies that have been, or will be,
24 implemented pursuant to this chapter.

25 (E) Estimated costs and savings attributable to activities that
26 have been, or will be, undertaken pursuant to this chapter.

27 (F) The workplan that the department is required to develop
28 pursuant to paragraph (5).

29 (c) Nothing in this section shall be construed to require sharing
30 of information that is prohibited by any other provision of law or
31 contractual agreement, or the disclosure of information that may
32 adversely affect potential drug procurement by any state agency.

33 SEC. 4. Article 5 (commencing with Section 110242) is
34 added to Chapter 2 of Part 5 of Division 104 of the Health and
35 Safety Code, to read:

36
37 Article 5. California R Prescription Drug Web Site Program

38
39 110242. (a) The California R Prescription Drug Web Site
40 Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2007 2008, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

~~(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d). If the federal government enacts, by October 15, 2006, procedures for individuals to obtain prescription drugs from international pharmacies, this paragraph shall not apply to the department Web site.~~

~~(5)~~
(4) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) ~~(1) The department's Web site shall include price comparisons of at least 150 commonly prescribed prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2): the state.~~

~~(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, the United Kingdom, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:~~

~~(A) Are licensed by the province or country, as appropriate, in which they are located.~~

1 ~~(B) Comply with the requirements of a nonresident pharmacy~~
2 ~~as specified in Section 4112 of the Business and Professions~~
3 ~~Code, except that for purposes of this section, all references to~~
4 ~~“state” in subdivision (d) of Section 4112 of the Business and~~
5 ~~Professions Code shall be deemed to refer to the province or~~
6 ~~other licensing jurisdiction in which the pharmacy is located.~~
7 ~~Compliance with this subparagraph shall be determined by the~~
8 ~~department in consultation with the California State Board of~~
9 ~~Pharmacy.~~

10 ~~(C) Require a prescription from a patient’s personal physician,~~
11 ~~who is licensed to practice in the United States.~~

12 ~~(D) Require the completion of a relevant medical history~~
13 ~~profile.~~

14 ~~(E) Require a signed patient agreement.~~

15 ~~(F) Ship prescription drugs in tamperproof original~~
16 ~~manufacturer containers to individuals in the United States,~~
17 ~~unless the consumer requests to receive the drug in a childproof~~
18 ~~container.~~

19 ~~(G) Include a physical address and pharmacy license number~~
20 ~~on its company Web site.~~

21 ~~(H) Do not furnish any of the following:~~

22 ~~(i) A controlled substance.~~

23 ~~(ii) A biological product, as defined in Section 351 of the~~
24 ~~Public Health Service Act (42 U.S.C. Sec. 262).~~

25 ~~(iii) An infused drug, including, a peritoneal dialysis solution.~~

26 ~~(iv) An intravenously injected drug.~~

27 ~~(v) A drug that is inhaled during surgery.~~

28 ~~(vi) A drug that requires refrigeration or cannot be safely~~
29 ~~shipped by mail.~~

30 ~~(vii) More than the prescribed amount of a drug or more than~~
31 ~~a three-month supply of any drug.~~

32 ~~(viii) A drug that the consumer indicates he or she has not~~
33 ~~previously taken.~~

34 ~~(ix) A drug for which there is no equivalent drug approved for~~
35 ~~sale in the United States by the federal Food and Drug~~
36 ~~Administration.~~

37 ~~(I) Sell only prescription drugs that have been approved for~~
38 ~~sale in the country in which the pharmacy is located by the~~
39 ~~agency responsible for ensuring the safety of prescription drugs~~
40 ~~in that country.~~

1 ~~(J) Comply with state law regarding the documentation of the~~
2 ~~pedigree of prescription drugs.~~

3 ~~(K) Do not require a consumer to sign a waiver of liability or a~~
4 ~~release of liability for a negligent act by the pharmacy.~~

5 ~~(L) Maintain a service department to respond to consumer~~
6 ~~inquiries and provide information to consumers about how they~~
7 ~~may file complaints with the provincial or other applicable~~
8 ~~licensing authority.~~

9 ~~(M) Ensure that all physicians, pharmacists, and technicians in~~
10 ~~its employ are properly licensed and their licenses are in good~~
11 ~~standing.~~

12 ~~(N) Comply with all personal health and medical information~~
13 ~~privacy laws applicable to pharmacies located in California.~~

14 ~~(O) Any other requirement established by the department to~~
15 ~~ensure the safety, accessibility, and affordability of prescription~~
16 ~~drugs.~~

17 ~~(3) A pharmacy that seeks to be linked to the department's~~
18 ~~Web site pursuant to paragraph (2) shall apply to the department.~~
19 ~~The department may enter into a contract with a pharmacy that it~~
20 ~~determines meets the requirements of paragraph (2). A contract~~
21 ~~may be renewed annually upon payment of the fee specified in~~
22 ~~paragraph (5), provided that the pharmacy continues to comply~~
23 ~~with the requirements of paragraph (2).~~

24 ~~(4) The department may terminate a contract with, and delete~~
25 ~~an electronic link to, or information about, a pharmacy that the~~
26 ~~department determines no longer complies with the requirements~~
27 ~~of paragraph (2). The department shall review within 30 business~~
28 ~~days any information that it receives regarding a pharmacy's~~
29 ~~compliance with the requirements of paragraph (2) and shall~~
30 ~~determine whether the information constitutes grounds for~~
31 ~~removal of the pharmacy from the Web site.~~

32 ~~(5) The department may assess a fee on international~~
33 ~~pharmacies that the department reviews pursuant to paragraph (2)~~
34 ~~to offset the cost of reviewing those pharmacies.~~

35 ~~(6) This subdivision does not apply to information about~~
36 ~~prescription drugs available from international pharmacies if the~~
37 ~~federal government enacts procedures, by October 15, 2006, for~~
38 ~~individuals to obtain prescription drugs from international~~
39 ~~pharmacies.~~

1 (e) The department shall ensure that the Web site established
2 pursuant to this section is coordinated with, and does not
3 duplicate, other Web sites that provide information about
4 prescription drug options and costs.

5 ~~(f) Any information, including the identity of an international~~
6 ~~pharmacy, to be posted on the Web site shall first be approved by~~
7 ~~professional staff of the department before it is posted.~~

8 ~~(g) The department shall include on the Web site a notice that~~
9 ~~informs consumers about state and federal laws governing the~~
10 ~~importation of prescription drugs and the federal Food and Drug~~
11 ~~Administration's policy governing personal importation. The~~
12 ~~notice shall also inform consumers that a pharmacy linked to the~~
13 ~~Web site is licensed in the country in which it is located and that~~
14 ~~the department has the right to remove a pharmacy from the Web~~
15 ~~site if it violates the requirements of paragraph (2) of subdivision~~
16 ~~(d) or the terms of any agreement between the department and~~
17 ~~the pharmacy. In addition, the notice shall include a statement~~
18 ~~that the state accepts no legal liability with respect to any product~~
19 ~~offered or pharmaceutical services provided by a pharmacy~~
20 ~~linked to the Web site.~~

21 *(h) Implementation of this section shall be contingent upon an*
22 *appropriation, if the department determines that the*
23 *requirements of this section cannot be implemented without*
24 *additional funding, in which case the department shall request an*
25 *appropriation from the Legislature for that purpose.*

26 *110243. (a) Contracts and change orders entered into*
27 *pursuant to this article and any project or systems development*
28 *notice shall be exempt from all of the following:*

29 *(1) The competitive bidding requirements of State*
30 *Administrative Manual Management Memo 03-10.*

31 *(2) The project authority requirements of Sections 4800 and*
32 *following of the State Administrative Manual.*

33 *(3) Part 2 (commencing with Section 10100) of Division 2 of*
34 *the Public Contract Code.*

35 *(4) Article 4 (commencing with Section 19130) of Chapter 5 of*
36 *Part 2 of Division 5 of the Government Code.*

37 *(5) Section 11.05 of, and Provision 6 of Item 4260-001-0001*
38 *of, Section 2.00 of the Budget Act of 2005 (Ch. 38, Stats. 2005).*

- 1 **(b)** *Change orders entered into pursuant to this article shall*
- 2 *not require a contract amendment.*

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